

Application No. 10/619,735
Response Dated February 14, 2007
Reply to Office Action of November 16, 2006

REMARKS/ARGUMENTS

1. Remarks on the Amendment

Claims 1-24 have been canceled, without prejudice,

New Claims 47-62 have been added to more specifically define Applicant's claimed invention. Antecedent basis of the new claims can be found in the Specification and the claims as filed.

More specifically, antecedent basis of Claim 47 can be found in Paragraphs 0006, 0016, 0025, 0031, 0062 and 0071, Fig. 2, and Example 1 of the Specification and Claims 1, 6 and 7 as filed.

Antecedent basis of linking moiety in Claims 47 and 50-52 can be found in the Paragraphs 0016, 0025 and 0095, and Example 1 of the Specification.

Antecedent basis of Claims 47-49 can be found in Paragraphs 0070 and Example 1 of the Specification.

Antecedent basis of Claim 53 can be found in Paragraph 0062 and Example 1 of the Specification.

Antecedent basis of Claim 56 can be found in Example 1 of the Specification and Claim 5 as filed.

Antecedent basis of Claim 57-59 can be found in Example 1 and Paragraphs 0086-0087 of the Specification.

Applicant respectfully submits that no new matter is introduced by the amendment.

2. Response to the Rejection under 35 USC §112, Second Paragraph

Claims 1-7, 10-14, 16 and 20-23 have been canceled. However, this rejection has been addressed in the new claims to comply with 35 USC §112, Second Paragraph.

3. Response to the Rejection under 35 USC §102(b)

Claims 1-7, 10-14, 16 and 20-23 have been rejected under 35 USC §102(b) as being anticipated by Bogen et al. (U.S. Patent No. 6,281,004). This rejection is respectfully

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traversed by the amendment.

For there to be anticipation under 35 U.S.C. §102, "each and every element" of the claimed invention must be found either expressly or inherently described in a single prior art reference. *Verdegaal Bros vs. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and references cited therein. See also *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1581, 230 USPQ 81, 84 (Fed. Cir. 1986) ("Absence from the reference of any claimed element negates anticipation."); *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). As pointed out by the court, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. *ATD Corp V. Lydall, Inc.*, 159 F.3d 534, 545, 48 USPQ 2d 1321, 1328 (Fed. Cir. 1998).

As positively recited in the new independent Claim 47, Applicant's claimed device comprising a) a target of a secondary antibody to be used in the assay; the target being bound on a first plurality of spatially defined sites on a substrate, and each of the first plurality of spatially defined sites having a different amount of the target; b) a secondary antibody conjugate comprising the secondary antibody and a ligand to be used in the assay; the secondary antibody conjugate being bound by a linking moiety on a second plurality of spatially defined sites on the substrate, each of the second plurality of spatially defined sites having a different amount of the secondary antibody conjugate; and c) an enzyme conjugate comprising an enzyme to be used in the assay and a binding partner specific to the ligand; the enzyme conjugate being bound by the linking moiety on a third plurality of spatially defined sites on the substrate, each of the third plurality of spatially defined sites having a different amount of the enzyme conjugate.

Applicant submits that the claimed subject matter is not disclosed, taught or suggested by the prior art of record. More specifically, Bogen et al fail to teach Applicant's claimed device that has a target of a secondary antibody, a secondary antibody conjugate, and an enzyme conjugate all bound on the same substrate.

Instead, Bogen et al. teach an assay device having thereon one or more target analytes of the assay, more specifically, antigens or synthetic peptides mimicking the

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antigens to be analyzed. In the quality control process, the assay device can be exposed to a reagent containing a secondary antibody and then a reagent containing an enzyme, as used in the assay of a biological sample. However, the secondary antibody and the enzyme are never bound, nor intended to be bound, on the assay device.

Therefore, the reference fails to anticipate or suggest Applicant's claimed invention.

With regard to Claims 48-62, these claims are dependent upon independent Claim 47. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claim 47 is not anticipated by the prior art of record, as such Claims 48-62 are submitted as being allowable over the art of record.

In view of the above, Applicant respectfully requests withdrawal of the rejection of under 35 U.S.C. §102(b).

Furthermore, Applicant submits that new Claim 47 is generic to the Species defined by the Examiner in the Office Action dated June 21, 2006. Applicant respectfully submits that upon the allowance of a generic claim, Applicant is entitled to consideration of claims to the species which are written in dependent form, or otherwise include all limitations of the allowed generic claim as provided by 37 CFR1.141.

It is respectfully submitted that Claims 47-62, the pending claims, are now in condition for allowance and such action is respectfully requested.

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

2/14/2007
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